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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,657	09/29/2004	Teruyuki Yatabe	029650-158	2288
21839	7590	11/03/2005	EXAMINER	
BUCHANAN INGERSOLL PC (INCLUDING BURNS, DOANE, SWECKER & MATHIS) POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			HUH, BENJAMIN	
			ART UNIT	PAPER NUMBER
			3767	

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/509,657	Applicant(s) YATABE ET AL.	
	Examiner Benjamin Huh	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01/27/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3-5 and 7 is/are allowed.
- 6) ☒ Claim(s) 1 & 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>09/29/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The continuing data for this application which is a 371 of PCT/JP03/03872 from the date 03/27/2003 and foreign application date of JAPAN 2002-097015 from filing date 03/29/2002 is acknowledged with an effective filing date of 03/29/2002.

Information Disclosure Statement

The information disclosure statement received on 9/29/2004 is acknowledged. The IDS meets the requirements of 37 CFR 1.97 & 1.98 and therefore references listed there in have been considered. It is also noted that the copies were transmitted by the International Bureau and were cited in an International Search Report in the corresponding PCT application.

Specification

The title of the invention is not descriptive. A new title that is clearly indicative of the invention to which the claims are directed is suggested to be made to cover the improvements of the "Injection Needle".

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract

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on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because the language of the abstract is of the form used in patent claims. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: The section in Table 2 on page 24 of the specification states "Inventive Example" in the table where instead it should state "Comparative Examples". Appropriate correction is required.

Drawings

It is stated in the specification by the applicant on page 1 first paragraph of the Background Art section that FIG. 7 is a plan view of the edge surface of a lancet point structure of a conventional injection needle, which is believed to convey prior art. Figure 7 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified

and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claims

Claims 2 & 4 state that "... the minimum distance between said needle point and said central plane is in the range from 3 to 20% of the maximum outside diameter of said first ground facet in the direction of a minor axis therefor." When considered in the broadest reasonable context, the range of the distance between said needle point and said central plane is found to be 3 to 100% of the maximum outside diameter of said first ground facet in the direction of a minor axis therefor due to the fact that the range of the minimum distance was only required to be 3 to 20% of the maximum outside diameter of said first ground facet. Therefore, the claims will be read that the range of the distance between said needle point and said central plane is 3 to 100% of the maximum outside diameter of said first ground facet in the direction of a minor axis therefor.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 & 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon (US Patent No. 5064411) in view of Kaneko (US Patent No. 6517523). Gordon

discloses a needle which contains a "needle point" not present on the central plane "...wherein the minimum distance between said needle point and said central plane is in the range from 3 to 20% of the maximum outside diameter ...". Although Gordon does not have at least 3 "ground facets" attention is directed to the Kaneko reference which discloses a "Needle for injection syringe and method for manufacturing the same" that contains 5 "facets" at different angles which allows for a needle which "...eliminates the maximum values of resistance force at the ridges and which reduces the pain with an excellent cutting quality". Therefore, to modify the Gordon needle to have more facets would have been obvious to one of ordinary skill in the art at the time of the invention in order to render it more patient friendly by reducing the amount of pain endured by the needle.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon (US Patent No. 5064411) in view of Kaneko (US Patent No. 6517523). Gordon discloses a needle which contains a "needle point" not present on the central plane "...wherein the minimum distance between said needle point and said central plane is in the range from 3 to 20% of the maximum outside diameter ...". Although Gordon does not have at least 3 "ground facets" attention is directed to the Kaneko reference which discloses a "Needle for injection syringe and method for manufacturing the same" that contains 5 "facets" at different angles which allows for a needle which "...eliminates the maximum values of resistance force at the ridges and which reduces the pain with an excellent cutting quality". Therefore, the needle found in Gordon in view of Kaneko can

have the same structure as the applicant's and it would be the examiner's position that the apparatus would be fully capable of the function claimed in claim 6.

Allowable Subject Matter

Claims 3-5 and 7 are allowed. The following is an examiner's statement of reasons for allowance: the independent claim 3 which consists of an "injection needle having an edge surface comprising three ground facets formed on a distal end of a needle tube to provide a needle point, characterized in that one of the ground facets which is remotest from said needle point is regarded as a first ground facet, and the other ground facets as a second ground facet and a third ground facet; and an angle α between said first ground facet and a central axis of said needle point, an angle ϕ between said second ground facet and the central axis of said needle point, and an angle θ between said third ground facet and the central axis of said needle point are related to each other by: $\alpha < \phi$, $\alpha < \theta$, and $\phi \neq \theta$ " is allowable due to the novel and non-obvious nature of the claim in which there is a 3 facet injection needle that discloses the 2 facets closest to the tip to consist of different angled facets which causes the facets to have different lengths as well as forcing a deviation of the needle tip from the normal central axis. Also, since claims 4, 5, and 7 are dependent on independent claim 3 and are further limiting to claim 3 these claims are deemed to be allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Saito (US Patent No. 5968022), Doyle (US Patent No. 5752942), and Baldwin (US Patent No. 3071135) are cited for showing other "injection needles" with multiple facets at various angles.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


BH


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